
CENTER ON DRUGS & PUBLIC POLICY

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Policy Sciences Graduate Program
and the School of Pharmacy



AN INTRODUCTION TO THE PRACTICE OF PHARMACY IN THE UNITED STATES

Prepared for the Operations Branch, Health Care Financing
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1. INTRODUCTION AND OVERVIEW

1.1: Pharmacy in America's Health Care System

The procurement, storage, preparation and distribution of prescription (legend) and non-prescription (OTC) medications in the United States has been the time-honored responsibility of the profession of pharmacy. While evolving and responding to changing times, the profession takes major responsibility for assuring the safe-keeping and effective distribution of drugs and drug products to a variety of recipients in America's health care system. In addition, pharmacists play a variety of roles where expertise in pharmaceuticals is demanded.

Among the nations of the developed Western world, the United States boasts one of the most accessible and geographically expansive systems of drug supply management. Moreover, the pharmacy manpower force in the U.S. is broadly distributed throughout health care facilities and communities responding to the needs of patients and prescribers alike in a variety of practice settings. Apart from those geographic areas of the country which have been traditionally underserved by health care professionals, pharmacies may be found in most communities of the nation; almost all hospitals are served by pharmacists.

Like all of the health professions, the profession of pharmacy is undergoing significant change with respect to role function

and responsiveness to changes occurring in the organization, financing and delivery of health care services in the United States. Most pronounced of these changes is the move of the profession, begun approximately twenty years ago, toward greater clinical involvement in the drug use process. The latter involvement expands the application of pharmacy's broader "knowledge system" to more direct care of the patient using pharmaceuticals, in addition to the traditional role in the distribution of a drug product. Specifically, this clinical role centers on assuring an appropriate drug therapy plan that coincides with principles of rational therapeutics, proper patient education and the subsequent monitoring of drug effects in the patient.

With an ever-expanding complex armamentarium of drugs and drug products, the prescriptive process is correspondingly becoming more complex. Hence, the role of the pharmacist is likely to become more visible in direct patient-care involvement beyond fulfilling the more traditional role of assuring that appropriately prepared, labeled and packaged drug products reach the patient. This evolving professional role, while more clearly witnessed in hospitals and extended care facilities to date, is involving increasing numbers of pharmacists practicing in community pharmacies who are directing their efforts to greater management of the patient's drug therapy in conjunction with the prescribing physician. The latter role's further refinement in

the community is largely dependent on the economic viability of the practice setting since the profession continues to be reimbursed on the basis of the dispensing of products rather than the provision of value-added services. Extensive corporatization of the practice of pharmacy in the community, characterized by the growth of chains, has also impeded a more rapid expansion of the pharmacist's clinical role due to a disproportionate interest by corporate managers in sales and profitability at the expense of patient care services.

1.2: Drug Use in the United States

In 1987, approximately 1.6 billion prescriptions were dispensed in community pharmacies and other out-patient settings in the private sector at a total cost of approximately \$25 billion. An additional \$5 billion of drugs were used in American hospitals and \$8 billion of non-prescription drugs sold in the United States. The per capita drug expenditure in the U.S. for 1987 approximated \$160. The U.S. is characterized as one of the highest per capita drug consuming nations in the developed world.

Drugs are increasingly becoming the first therapy of choice in those disease problems that respond to appropriate drug treatment. Consequent to the implementation of a prospective reimbursement system, length of stay in hospitals has decreased dramatically over the past five years. Much of the ability to

discharge patients earlier relies on a more aggressive drug treatment plan. The advances of drug discovery have allowed a number of disease problems previously only treatable with invasive techniques, to be appropriately managed with drug treatment. Advances in drug development have also allowed previously untreatable diseases to be treated with drugs.

Non-prescription drugs are available in a variety of outlets including pharmacies. This availability has corresponded with a social movement toward greater self-care and treatment. Several drugs previously only available upon order of a prescription have been approved by the U.S. Food and Drug Administration (FDA) for sale over the counter (OTC). This trend will likely continue for those drug entities whose safety for self-administration has been established and where labeling for non-prescription use can be effectively constructed so as to minimize harm to the patient. The profession of pharmacy is on record in support of creating a third-class of drugs: drugs that would be transitory between legend and OTC status and for sale only under the supervision of a pharmacist. This policy has been adopted due to the profession's concern that the public be safeguarded for the use of drugs for which large self-medicating populations have not been evaluated. A change in Federal laws is necessary to effect such change; however, the State of Florida allows pharmacists to provide certain legend drugs to patients without prescriptions. Several other states (eg.

California and Washington) allow pharmacists to provide legend drugs within approved protocols developed between pharmacists and physicians.

The concept of a third class of drugs is vigorously opposed by the Proprietary Association (PA), the trade association of OTC manufacturers that markets its products through 700,000 non-pharmacy outlets (eg. grocery stores, gas stations, vending machines).

1.3: Distributive and Clinical Services

The profession has partitioned its services into two major categories: distributive services and clinical services. The former refers to the role more traditionally associated with the practice of pharmacy; namely, procuring, preparing, labeling and packaging a drug dosage form and dispensing it to the right patient. This has been the "main-stay" role of American pharmacy and indeed, it is a role which has been effectively implemented throughout the nation. Through a complex marketing and distribution network, pharmaceuticals in the U.S. are broadly available and accessible to the American public. In hospitals and nursing homes (and other institutions of care), this role is effected mainly through "unit dose" distribution systems wherein individual patient doses are prepared, packaged and labeled for direct administration to the patient. These institutions also have a significant pharmacy commitment to the

preparation of intravenous solutions and drug admixtures. In the community practice of pharmacy, the drug distribution activities of pharmacists is largely responsive to the direct prescription order written or telephonically transmitted by physicians and other state authorized prescribers and brought to the pharmacy by the patient.

Clinical pharmacy services are offered in conjunction with these distributive services to assure rationally applied and managed drug therapy. A variety of schemes have been effected to date in order to assure rational therapeutics with drugs through the clinical involvement of the pharmacist. Documented cost-savings, legal risk management, rational therapeutics and better patient outcomes have been associated with the implementation of clinical pharmacy services in institutions. Current concerns about the cost of drug therapy have led managed care administrators to look to clinical pharmacy practice to be applied to other areas of care (eg. Health Maintenance Organizations). The increasing litigation associated with irrational drug therapy has also been a stimulus to apply principles and practices of clinical pharmacy to the out-patient setting.

The application of clinical services relies on a significant knowledge base and effective system of communication between prescriber and pharmacist. While institutions of care have been

more amenable and accommodative to such inter-professional interaction, the trends to quicker and broader ambulation of the sick will stimulate mechanisms whereby clinical practice will expand to the ambulatory care setting. Resolution of an appropriate reimbursement mechanism will perhaps have the greatest effect on expanding this component of pharmacy practice in the community.

1.4: Business and/or Profession?

Tradition and context have associated the profession of pharmacy with the distribution of products. Such a strong orientation on products, that centers on their procurement and distribution, has structured a payment mechanism that focuses on reimbursing pharmacists for the cost of acquiring the product and some margin of profit. Prescriptions in community pharmacies are priced by taking into account the cost of acquisition and some predetermined (usually not systematically developed) mark-up. Such a pricing scheme has not given community pharmacies sufficient capital to permit to limiting their functions to just filling and dispensing prescriptions; therefore, they have turned to selling other merchandise. In short, it has been easier to make money competing as specialized retailers than to develop clinical pharmacy services.

Hence, contemporary pharmacies in the community have been retailing establishments in which some health services are made

available in conjunction with the filling of prescriptions.

This context also reflects the unique nature of the American market-place and its development as part of the western frontier expansion. Drug stores were the only early repositories for chemicals, sundries and imported herbals as the frontier expanded. In contemporary times, the extensive expansion of mass merchandising and other retailing enterprises has included pharmacy departments in order to serve as inducements to expanded merchandise sales. The majority of the public, particularly that segment of the public using prescription medications, is exposed to this entrepreneurially-based setting. This view has been fostered by the corporatization of pharmacy alluded to earlier. The profession is thus characterized by public opinion as both business and profession. While other health professions are evolving toward a similar model, pharmacy in the community has been characterized in this fashion for most of its contemporary history. Until the professional service of the pharmacist becomes more institutionalized and thus reimbursed, the practice of pharmacy in the community will likely be continued in a profoundly business directed fashion.

1.5: Current Trends

As pressures to contain costs in America's health care system become more wide-spread, the profession of pharmacy is of course not immune from these impacts. Indeed, cost-containment

pressures have always existed in the community practice of pharmacy because of its place in the retail marketplace.

Hospital pharmacy practice has been affected by cost-containment efforts in hospitals due to the changing reimbursement policies of third party carriers; however, this is a more recent trend. Significant concern exists in the profession about the appropriate balance between cost-containment and the offering of quality pharmacy services. This concern is exacerbated by the rapid increase in drug procurement costs (eg. manufacturer's prices), increasing pharmacist salaries due to manpower shortages, and the increased cost of doing business.

The increasing complexity of drug therapy and available drug products places greater knowledge demands on the pharmacy community. Most states now have mandatory continuing education requirements. Professional associations continue an aggressive expansion of continuing education symposia through a variety of on-site and self-instructional programming. Schools of pharmacy also have a significant commitment to the professional community for continuing, post-graduate education.

An increasing proportion of female practitioners in pharmacy has been evidenced over the past ten years. Current enrollment of females in schools and colleges of pharmacy exceeds sixty percent. Given the known productivity issues surrounding

largely female professions, there is a concern about the current and future responsiveness of the pharmacy workforce. Part of this concern is being evidenced in the expanding discussions (and utilization) of pharmacy technicians in the profession.

Automation and mechanization of the prescription filling and dispensing process is expanding. With the advent of computer applications to this process, it is forecasted that many of the routine tasks currently undertaken by pharmacists will be replaced by automated systems. Concern among some sectors of pharmacists that they will be replaced by machines has been expressed. Other pharmacists believe that expanded automation will give them greater freedom to communicate with prescribers and patients and thus expand their clinical involvement.

Competition in the community sector, while always of concern to pharmacy owners, has increased with the advent of mail-order prescription services, expanding ambulatory care centers as part of hospital "product" diversification, involvement in pharmacy by mass-merchandising retailers and physicians who sell medications to their patients. On the other hand, growth in specialized pharmacy practice in the community and in the hospital has been responsive to the ever increasing complexity of drugs and drug therapy. Home based intravenous drug therapy, for example, requires such a specialized pharmacy.

Scientific knowledge and instrumentation now allows for the more accurate dosing of patients with drugs that have a close margin between efficacy and toxicity. Hence, pharmacists are increasingly involved in the application of dosing protocols for such drugs. It is likely that this technology will expand to the community through the advent of "strip-tests" which indicate drug dose level in blood or urine.

Pharmacists are increasing their involvement in patient education. This trend is due in part to i) recognition that even with the number of sophisticated medications available, patient morbidity remains a problem due to non-compliance with medication regimens, ii) consumers who are more sophisticated and sometimes skeptical, desire more information and iii) certain federal mandates for education for drugs such as diethylstilbestrol, Accutane and contraceptive control medications.

2: PHARMACY AS A PROFESSION

2.1: Profession as a Sociological Concept

The origin of pharmacy as a profession dates to antiquity without particular distinction between the preparation of medicaments and the diagnosis and treatment of disease. Separation of pharmacy and medicine as two distinct professions occurred in Europe between the 13th and 17th century. In the United States, no particular distinctive decree separated the

practice of medicine from that of pharmacy. This was perhaps accomplished with the advent of medical and pharmacy practice acts around the turn of the 20th century.

Certain criteria have been developed over time by sociologists interested in characterizing professions and measuring certain occupations against these criteria. Most important among the criteria marking a profession are: a unique body of knowledge, specific skills and professional standards, a distinct code of ethics and a prescribed educational program that is specifically directed at the skills and knowledge required to ably conduct their respective functions. Also, health professionals have an explicit and implicit covenant to use their knowledge in the protection of the patient and thus to do no harm.

In the case of pharmacists, the covenantal relationship with the patient is centered on assuring that no harm is done when medications are prescribed, administered and otherwise used by the patient. This relationship is manifested in the attention to accuracy and appropriateness that is given to the various aspects of the drug use process by the pharmacist. The ethical and professional duty to protect the patient from harm and to optimize the use of drugs by providing appropriate "pharmaceutical care" is the underlying professional "raison d'être" of the pharmacy profession.

2.2: Evolving

The profession of pharmacy has been studied by several occupational sociologists in order to determine its sociological status as a profession. Of particular interest in sociological circles has been the professional and business duality. And indeed, pharmacy does represent this duality in greater visible fashion than most other health professionals. Its closest counterpart in this regard is optometry. Little distinction has been made in the sociological literature between the professional status of pharmacists practicing in different settings. Hence, sociological illumination of the pharmacist's status as a professional in a broader professional context is not available.

Autonomous practice and cultural legitimization of authority are additional markers of a profession. These notions are perhaps embedded in the clinical practice of pharmacy. As the profession evolves to greater clinical involvement, it is likely that autonomous practice will evolve; that is, greater independence from the physician. This evolution is already being seen in certain specialty practices of pharmacy (eg. oncology, organ transplantation) and in those states which allow pharmacists greater latitude in the management of patients within certain treatment protocols. Cultural authority for the practice of pharmacy varies depending on site of practice and personal relationships built between individual patients,

pharmacists and prescribers.

As the profession of pharmacy gains greater respect for its capabilities and knowledge base, it is likely that greater interprofessional collaboration will be seen. A team-approach to the pharmaceutical care of the patient is already in place in a number of settings.

2.3: Corporatization

Because of its strong affiliation with the procurement and distribution of PRODUCTS, the profession of pharmacy has perhaps had a greater affinity for early corporatization than other health occupations. Beginning in the early 1950's, aggregates or "chains" of pharmacies were constructed by corporate entrepreneurs responding to the post-World War II expansion and suburbanization of city areas. This movement continues today at an even greater pace as shopping and demographic patterns of the population change. Easy access, competitive pricing and quick service have been the hallmarks of corporate success in the pharmacy marketplace.

However, this success has been at the expense of appropriate and quality patient care. Mass filling of prescriptions in the corporate sector has placed the pharmacist in these settings in conditions not much different from those of piece-work, assembly line worker even though the product of their work efforts have

substantial potential for harm if the prescription is not properly interpreted, filled and dispensed. Most importantly, this emphasis on quantity rather than quality has become such a wide-spread publicly visible phenomena that a broad patient expectation for quality pharmacy services does not exist.

This corporate evolution has created a receptive environment for alternatives to obtaining prescriptions; namely, the mail order house and the physician's office. However, the environment of the "corporate practice" of pharmacy is becoming more competitive and hence, a focus on service is emerging. While competition on price alone has its bottom limits, emphasis on cost-effective service has less clear limits. Hence, advertising to the public on the basis of service may be the next wave of competition among a large field of players.

2.4: Marginal, Quasi or Real?

In the context of the issues presented in the narrative above, the question might be appropriately asked: is pharmacy a profession? Sociologists have characterized it as a "marginal profession" and as a "quasi-profession"; however, as noted before, these taxonomies have been based on a limited view of the profession's involvements and most of the characterizations are now over twenty years old.

The job functions of a pharmacist are characteristic of the

calling of a profession. Some settings in which this calling is applied may not meet the sociological standards for the practice of a profession. However, this needs to be balanced against two major issues: i) the difference in practice between and within settings of practice and ii) the expanding numbers of pharmacists whose job functions and responsibilities provide substantial value-added service to the patient and prescriber.

3: PHARMACY SETTINGS AND TYPES OF PRACTICE

3.1: Community Pharmacy

Independent Pharmacies

Approximately 40,000 such pharmacies exist in the United States. They are characterized by solo or partnership ownership and are in all respects, small businesses. Most have a defined clientele who live or work close by and look for a continuous and evident patient relationship with a known pharmacist. While there was a decline in such settings, recent data seem to indicate that there is a resurgence of growth, especially in the numbers of specialty oriented pharmacies (eg. home intravenous therapy, durable medical supplies and pharmaceuticals, and pharmacies serving nursing homes exclusively).

Independent Chain Pharmacies (Small Chains)

Counted among the 40,000 independent pharmacies in the U.S., these companies are generally individually owned or owned in partnership and have no more than five units. Their orientation

is similar to that of the independent pharmacy.

Chain Pharmacies

Approximately 17,000 such units exist in the U.S. They are corporately owned either as a free standing company or a subsidiary of larger companies. Open approximately eighty hours per week, these stores are generally retailing environments that have a pharmacy department located in them.

Mass Merchandising Stores

Counted among these are the likes of K-Mart, J.C. Penney's and Sears and Roebuck. The pharmacy department represents a small component of the total business enterprise. The focus in these settings is on one-stop shopping and a bundling of accessibility to prescription drugs with other available merchandise and sundries. No accurate number of these settings exists although it is estimated that 2,500 such facilities presently are in operation.

Food/Grocery Stores

There are approximately 2,500 pharmacies situated in food/grocery stores. This segment of the market is growing according to the Food Marketing Institute.

3.2: Institutional Pharmacy

Acute Care Settings

There are approximately 6,800 acute care hospitals in the U.S. including federal and state facilities. Pharmacy services in such settings provide for the totality of drug service requirements ranging from the procurement of pharmaceuticals and intravenous solutions to their distribution to individual patients and to patient care management. Such settings often engage pharmacists in drug information services, formulary development and implementation and pharmacokinetic monitoring.

Ambulatory Care Clinic Settings

With decreasing length of stay and increasing competition for patient markets, a number of acute care facilities have expanded into the ambulatory care market. In a variety of instances, this expansion has included the establishment of pharmacies in order to provide a broader range of services. The Hospital Pharmacy Service thus is responsible for both in-patient and out-patient pharmacy services.

3.3: Long-Term Care Facilities

About 27,000 long-term care facilities have been identified in Vital Statistics Reports. In the case of nursing homes and extended care facilities, pharmacy services are most often provided through contracts with existing community pharmacies. Some facilities have their own "in-house" pharmacies but this is the exception rather than the rule.

3.4: Mental Health Facilities

Approximately 14,000 such facilities exist in the U.S. according to Vital Statistics Reports. Pharmacy services in such settings are either provided through "in-house" services or by contract with local community-based pharmacies.

3.5: Local, State, Federal Government

Uniformed Services

U.S. Army

U.S. Air Force

U.S. Navy

U.S. Public Health Service

Indian Health Service

U.S. Veteran's Administration

Approximately \$600 million is spent annually on pharmaceutical in 170 care facilities operated by the Veteran's Administration. The VA has 3,200 pharmacists on its staff.

Agencies

National Institutes of Health

U.S. Food and Drug Administration

City Health Clinics

County Health Clinics

Campus Student Health Services

3.6: Pharmaceutical Industry

Pharmacists are employed in a variety of areas within the pharmaceutical industry such as marketing and sales, quality control, production and product development. More recently, pharmacists are being hired to operate and manage drug information programs and to participate in the clinical trial activities associated with new drug evaluation and testing.

3.7: Pharmaceutical Education

Schools and colleges of pharmacy in the U.S. employ approximately 2,700 full-time and 712 part-time faculty. Approximately half of these faculty members are pharmacists.

3.8: Miscellaneous

Pharmacists are also employed in other settings such as organized/managed health care organizations, State Medicaid and Pharmaceutical Assistance Programs, professional organizations and law enforcement.

4: PHARMACISTS

4.1: Social characteristics

From several studies concluded to date, the profession of pharmacy draws its matriculants largely from upper lower class to lower middle class social groups. The profession is an accessible occupation for first generation immigrants, from which a substantial portion of its ranks have been recruited. However,

enrollments of minorities have been low. During the past fifteen years, increasing numbers of females have been attracted to pharmacy. Present enrollments indicate a sixty percent enrollment of females. This latter phenomenon is in stark contrast to a five percent enrolled female population just twenty five years ago. Occupational inheritance is not wide-spread in pharmacy.

4.2: Demography

The Sixth Report to the President presents estimates that there are presently approximately 162,000 practicing pharmacists in the United States and further states that there is a balance between the demand for pharmacists and the available supply. Some controversy exists over these data and the assessment of supply and demand. Approximately 65 percent of practicing pharmacists are employed in community practice settings (independent and chain), 25% practice in institutions and the remaining 10% in educational institutions, the pharmaceutical industry and other areas of related pharmacy.

4.3: Current Demand

Demand for pharmacists is high as reflected by job openings, competitive salaries, extensive advertising for pharmacists and aggressive recruitment. Documented shortages exist in all sectors of pharmacy, including the military services. Concern exists in the profession about adequate responsiveness to demand

for quality pharmacy services in the wake of i) shortage in the numbers of pharmacists and ii) short supply of specific talents (eg. clinical skills).

4.4: Current Supply

The supply of pharmacists available in the U.S. today is the subject of extensive investigation by a joint Pharmacy Manpower Committee organized and operated by representatives of several of pharmacy's professional organizations. The last national census of pharmacists in the U.S. was completed in 1974 and current, accurate data on the supply of pharmacists is lacking. Projections made by the Bureau of Health Manpower, U.S. Department of Health and Human Services, are based on a series of assumptions which are currently under scrutiny (eg. mortality, job separation, female FTE productivity) given the shortages of pharmacists that are reported all over the nation.

5: PHARMACY EDUCATION

The 74 accredited schools and colleges of pharmacy in the U.S. enroll approximately 27,000 students and graduate about 5,800 per year. The entry level degree is either the Bachelor of Science in Pharmacy (B.S.) or the Doctor of Pharmacy (Pharm.D.) degree with the latter requiring at least six years of University study and the former requiring five years of study. Ten of the 74 schools of pharmacy offer only the Doctor of

Pharmacy degree while an additional 22 allow students to choose and then track either into the B.S. or the Doctor of Pharmacy degree. The trend is to an expansion of curricular requirements in response to greater scientific and clinical knowledge required of the pharmacist. As the curricular requirements expand, the trend is to offer the Doctor of Pharmacy degree as the entry-level credential.

Seventy percent of the schools also offer graduate degrees (M.S. and/or Ph.D.) in the pharmaceutical sciences, including pharmacology, pharmaceuticals, pharmaceutical (medicinal) chemistry and pharmacy administration. Colleges of pharmacy are accredited by the American Council on Pharmaceutical Education. All of the colleges and school of pharmacy in the U.S. and Puerto Rico are presently accredited and institutional members of the American Association of Colleges (AACCP).

6: LEGAL CONTROL OF THE PRACTICE OF PHARMACY

6.1: Constitutional versus State Police Powers

The U.S. Constitution separates the rights of the states from those of the federal government. One of these separate rights is the granting of police powers to the states. With regard to professions and occupations, the states have the rights, responsibility and authority for controlling the practice of the professions. While certain federal laws affect practice in the professions, the stipulation of duty and the control of function

rests with the states.

6.2: Federal Law

The profession of pharmacy is affected by a number of federal laws among which the Federal Food, Drug and Cosmetic Act and the Controlled Substances and Narcotics laws are pre-eminent. The basis for federal involvement is that most drug products move in interstate commerce. Since almost all of the products and goods that the profession of pharmacy is involved in are in fact handled through interstate commerce (manufacturing ingredients, packaging, etc.), federal laws play an important part in practice. Several laws governing business, monopoly, trade, etc. also apply.

6.3: State Law

Several state laws apply to the practice of pharmacy. These include relevant State Practice Acts, particularly the respective State Pharmacy Practice Acts, State Controlled Substance and Narcotic Acts, State Food, Drug and Cosmetic Acts, State Public Health and Facilities Acts and other laws governing hypodermic syringes, poisons, etc. State pharmacy practice acts stipulate licensure requirements for pharmacists and pharmacies, standards for due care, operational requirements for pharmacies and other specific areas affecting the public health. Boards of Pharmacy administer these Acts.

6.4: Practice Standards

The American Pharmaceutical Association, in collaboration with the American Association of Colleges of Pharmacy, developed and published Standards for the Profession of Pharmacy in 1979. These are presently being reviewed and updated by a joint Task Force of these organizations. The American Society of Hospital Pharmacists establishes standards of practice and guidelines specific to hospital pharmacy practice. Similar practice standards have been developed for consulting pharmacists by the American Society of Consultant Pharmacists. The American College of Apothecaries also has Practice Standards in place.

6.5: Court Opinion

Court interpretation of State and Federal law as it applies to pharmacy practice is not extensively developed largely because heretofore the profession of pharmacy has not been involved in extensive litigation. Recently however, court argument about the "duty to warn" patients about potential negative effects of drugs has been evident. Depending on the court, the circumstances of the case and the legal history of a particular state, the court opinion is mixed with respect to placing such duty on the pharmacist.

7: PROFESSIONAL PHARMACY ORGANIZATIONS

7.1: American Pharmaceutical Association (APhA)

Pharmacy's oldest professional organization, the APhA attempts to

represent the broad interests of the profession. Its membership (including students) stands at approximately 35,000 individuals drawn from all areas of practice. One major Spring meeting each year for educational and policy setting purposes is offered by the APhA in addition to regional meetings which are usually offered in the Fall of the year.

CEO: John F. Schlegel

202/628-4410

7.2: ASHP (American Society of Hospital Pharmacists)

This organization represents pharmacists practicing in hospitals, although its membership and interests extend to all institutional settings (hence the recent adoption of the initials ASHP as its official name. It has approximately 20,000 members and offers two major meetings per year, one of which focuses on clinical topics. Its clinical meeting (Clinical MidYear) is held in the first week of December while its annual business (policy setting) meeting is usually held during the second week of June.

CEO: Joseph A. Oddis

301/657-3000

7.3: National Association of Retail Druggists (NARD)

Founded toward the latter part of the 19th century, the NARD centers its activities on the independent community pharmacy and represents the entrepreneurial and professional interests of these entities. It boasts about 30,000 members, all of whom are

owners or partners in independent pharmacies. Its annual meeting is usually held during the first week of October and a buying show is sponsored in the Spring.

CEO: Charles M. West

703-683-8200

7.4: American Association of Colleges of Pharmacy (AACP)

This is the only organization representing colleges and schools of pharmacy and their respective faculty members, administrators and staff in the U.S. Its membership is composed of 1,500 individual members and 74 institutional members. The Council of Deans meets annually in March while the educational and policy meeting is held during July.

CEO: Carl E. Trinca

703/739-2330

7.5: American Society of Consultant Pharmacists (ASCP)

The ASCP represent those pharmacists who serve as consultants to nursing homes and other types of extended care facilities. It has approximately 2,000 members and offers an educational meeting in the Spring.

CEO: R. Tim Webster

703/920-8492

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7.6: American College of Apothecaries (ACA)

This organization represents those pharmacies which meet certain

professional specifications; namely, fully professional pharmacies that do not sell anything beyond those products directly related to health care. Its membership stands at about 1,000. It sponsors an annual business and educational meeting in the spring of the year.

CEO: Delton C. ("DC) Huffman

901/528-6037

7.7: National Pharmaceutical Association (NPhA)

The NPhA is the professional society in pharmacy representing the interests of black pharmacists. Housed at Howard University, College of Pharmacy, its membership maintains about 500 minority (black) pharmacists. Its annual meeting is held during the first week of August.

CEO: James N. Tyson

202/636-6530 or 202/328-9229

7.8: American College of Clinical Pharmacy (ACCP)

This organization has strict membership requirements limited to those individuals who possess advanced clinical skills and practice these skills as their major activity. Its meeting in July focuses sharply on clinical research.

CEO: Robert M. Elenbaas

816/556-3112

7.9: American Foundation for Pharmaceutical Education (AFPE)

This is a charitable organization which draws its support from both individual and corporate members. Its fund-raising efforts are targeted towards the pharmaceutical industry and funding derived from these efforts supports the American Council on Pharmaceutical Education, the American Association of Colleges of Pharmacy and provides fellowships to students pursuing graduate studies (M.S. and Ph.D.) in the pharmaceutical sciences.

CEO: Richard E. Faust

201/561-8077

7.10: National Association of Boards of Pharmacy (NABP)

The boards of pharmacy and their members from 48 states, the District of Columbia and Puerto Rico, compose this organization. California and Florida are not members because the by-laws of the NABP require national reciprocity of pharmacist licensure and these two states do not allow such open reciprocity (these states require full examination rather than honoring reciprocal licensure). The annual Spring meeting centers on issues of public policy and law related to the practice of pharmacy and the distribution of drugs. It has about 500 members, all of whom are members and/or executives of their respective State's board of pharmacy.

CEO: Carmen Catizone

312/698-6227

7.11: National Association of State Pharmacy Association

Executives (NASPAE)

As the name implies, this is a gathering of individuals who serve as the executives of State pharmacy associations. These individuals meet in conjunction with the annual meeting of the American Pharmaceutical Association in order to share expertise and develop policy strategies.

CEO: Paul Galanti

804/355-7941

7.12: American Council on Pharmaceutical Education (ACPE)

This is the accreditation body for schools and colleges of pharmacy in the United States and Puerto Rico. It is approved by the Council on Post Secondary Education (COPA) and thus serves to apply the principles of accreditation outlined by the U.S. Secretary of Education. School and college of pharmacy accreditation operates on a six year review cycle with required annual reports. ACPE is the only such organization in the world.

CEO: Daniel A. Nona

312/664-3575

7.13: Joint Commission on Pharmacy Practice (JCPP)

The JCPP meets quarterly and is composed of each of the practice organizations: American Pharmaceutical Association, ASHP, National Association of Retail Druggists, American College of Apothecaries, and the American Society of Consultant Pharmacists. The American Association of Colleges of Pharmacy and the National

Association of State Pharmacy Association Executives are included as Affiliate Members. The JCPP serves as a forum for discussing issues of mutual concern in the profession and, where agreement can be reached, develops joint policy on professional matters. The chief executive and elected officer of the respective member and affiliate organizations compose the JCPP.

8: TRADE ORGANIZATIONS WITH INFLUENCE ON THE PROFESSION OF PHARMACY

8.1: Pharmaceutical Manufacturers Association (PMA)

The PMA is composed of "more than 100" manufacturing firms that produce "more than 90 percent of the prescription drugs used in the United States". It represents the "brand-name", research-intensive drug industry in the U.S. with a number of its members being multinational in scope; but PMA member companies have the largest share of the market for generic drugs. It has a strong and financially viable lobbying presence at the federal and state level. Its legislative aims are to minimize federal and state restriction on the industry with particular emphasis on non-restrictive sales. It has historically opposed governmental intervention in medical practice, restrictive state formularies and more recently, lobbied extensively to assure an open-market approach to the Catastrophic Coverage Act of 1988.

CEO: Gerald J. Mosinghoff

202/835-3400

8.2: National Association of Chain Drug Stores (NACDS)

This organization is composed of approximately 150 firms representing 18,000 pharmacies. Interests of the Association lie broadly in retail merchandising with a lesser interest in pharmacy practice and pharmacy.

CEO: Ronald L. Ziegler

703/549-3001

8.3: Generic Pharmaceutical Industry Association (GPIA)

This is the counterpart manufacturing trade association for those companies whose major focus is the production of generic prescription drug products. It is the antithesis of the PMA in that it represent "non-brand" interests and aggressively postures cost advantages of this industry.

CEO: Dee Fensterer

8.4: National Wholesale Druggists' Association (NWDA)

Made up wholesalers of prescription, non-prescription and sundry supplies, this organization is largely affiliated with independent pharmacies in order to meet their supply needs.

CEO: Charles S. Trefrey

703/684-6400

8.5: National Pharmaceutical Council (NPC)

There are 23 member corporations in the NPC, all of which belong to the PMA. These are by far the largest drug firms and, through

NPC, are single-minded in the promotion of the brand-name drug industry positions.

CEO: Mark R. Knowles

703/620-6390

8.6: The Proprietary Association (PA)

This organization represents those manufacturers who produce non-prescription medications. It has been a powerful lobbying force against restrictive marketing and merchandising of non-prescription drug products. Over 90% of non-prescription drugs marketed in the U.S. are represented by its member firms.

CEO: James D. Cope

202/429-9260

9: PHARMACY PERIODICALS

9.1: News and Current Events

American Druggist

Drug Topics

Weekly Pharmacy Reports (Green Sheet)

Food, Drug and Cosmetic Reports (Pink Sheet)

Drug Research Reports (Blue Sheet)

Dickinson's FDA

Chain Drug Review

9.2: Association Journals

American Pharmacy (APhA)

American Journal of Hospital Pharmacy (ASHP)

NARD Journal (National Association of Retail Druggists)

The Consultant Pharmacist (ASCP)

Drug Intelligence and Clinical Pharmacy (ACCP)

9.3: Privately Published Periodicals or Journals

Apothecary

Drug Store News

Hospital Formulary Management

Lippincott's Hospital Pharmacy

Medical Marketing and Media

Pharmaceutical Executive

Pharmacy Times

U.S. Pharmacist

10: PRACTICING PHARMACY

10.1: Drug Procurement

Per established standards and criteria of product and/or ingredient integrity, the pharmacist procures adequate supplies of drugs and other pharmaceutical products directly from manufacturers and/or wholesalers.

10.2: Drug Storage, Safety and Security

In order to maintain the integrity, safety and security of drugs and other pharmaceutical products, these agents must be stored in suitable environments ranging from climate controlled

shelving (eg. refrigeration for vaccines and suppositories) to highly secured storage (eg. for narcotics and other controlled substances).

10.3: Prescription Processing

This involves the receipt of the prescription, appropriate review of the prescription's contents against standards of ingredients, dose and quantity, maintaining required records, preparing correct labeling, preparing the requested drug(s) or extemporaneous product request, properly packaging the drug(s) or preparation within standards of packaging (eg. light, heat and humidity sensitivities), providing the packaged medication to the patient and consequently, rendering advice as to its appropriate use as well as cautions regarding side effects and contraindications. Note: in in-patient facilities this process is somewhat different because of the typical separation of the pharmacy from the patient and intermediary parties who are engaged in the drug distribution system within the hospital.

10.4: Extemporaneous Compounding

Less than 1% of the prescription orders processed in the U.S. require extemporaneous compounding; that is, the mixing together of active drug ingredients with appropriate excipients, solvents, flavoring agents, etc. Some specialized medical practice requests do require such compounding by the pharmacist; however, these are typically limited to dermatological agents,

special pediatric formulations, pain control compounds (eg. in terminal patients requiring higher doses) and in some gynecological conditions (eg. estrogen suppositories). Extensive extemporaneous compounding in the form of admixture (eg. several agents mixed into an intravenous solution) preparation is evident in hospital pharmacy practice and in home intravenous therapy (eg. hyperalimentation, antibiotic and chemotherapy, rehydration).

10.5: Pre-fabricated Dosage Forms

An efficient and effective drug manufacturing industry in the United States produces pre-fabricated dosage forms of a variety of tablets, capsules, solutions and novel dosage form delivery systems as per Good Manufacturing Practices dictated in federal law and regulation and product standards developed by the United States Pharmacopeia and the National Formulary. These products must meet packaging and labelling standards as well.

10.6: Prescription Dispensing

The dispensing function entails not only the transmission of the completed prescription order from the pharmacist to the patient but also includes patient counseling for assuring appropriate use and compliance with the desired drug regimen.

10.7: Therapeutic Management and Monitoring

The pharmacist is increasingly involved with and concerned about

the appropriate selection and use of the prescribed medication and assuring that desired outcomes are indeed met. Such active participation in quality assurance by the pharmacist may prevent serious mishaps or undesired effects. It may also enhance the original instructions provided the patient by the prescriber. A more comprehensive involvement of the pharmacist in the out-patient setting for these kinds of services is presently impeded by two major constraints: i) lack of a consistent record system that comprehensively contains relevant patient information and ii) the prescription acquisition patterns of the patient which typically involves more than one pharmacy and includes non-prescription medications oftentimes not purchased in a pharmacy.

10.8: Administration and Management

Regulatory and business practices require a substantial commitment of time by the pharmacist in administrative and managerial duties. Ranging from purchasing decisions to the management of personnel, the administrative burdens on the pharmacist are extensive. The rapid growth of third-party drug programs has increased record keeping enormously. Computers and other forms of automation as well as support staff are evolving to allow the pharmacist greater attention to professional responsibilities without neglecting administrative duties.

10.9: Drug Information

The literature, developed by independent investigators as well as the drug industry, on the varied aspects of drugs and pharmaceutical products is extensive in breadth and depth. Specialized drug information pharmacists are common in hospital pharmacies and serve as consultants to skilled care facilities and other areas of practice. Most of the pharmaceutical manufacturers have medical information divisions staffed by pharmacists who respond to information queries about drug products arising from the professional community. With the advent of computerized data bases, it is now possible to retrieve and contrast drug information literature in an electronic fashion. An expanding proportion of pharmacies now utilize computers for both administrative data processing and information retrieval.

10.10: Quality Assurance

The quality of pharmacy services in the U.S. has not been the subject of extensive research. As might be predicted, the quality of services is a function of the skills of the pharmacist, the settings in which those skills are applied and the nature of the relationships among pharmacist, prescriber and patient.

11: NEW AND EXPANDING ROLES FOR PHARMACISTS

11.1: Home Intravenous Therapy

This area involves the home-based administration of intravenous

dosage forms. Largely centering on antibiotics, chemotherapeutic agents (cancer treatment), nutritional support and re-hydration, such drug administration programs are said to be less costly than hospital based administration of these drugs while also allowing the patient to derive the benefits of being at home. Specialized pharmacies are being started to respond to this new area of technological capability and patient care.

11.2: Pharmacokinetic Drug Dosing

Certain drugs (eg. some antibiotics, asthma agents, anticoagulants, etc.) are extremely toxic if not appropriately titrated and dosed for the individual patient. Mathematical calculations based upon organ function, blood volume and rates of drug elimination, allow the patient to be individually dosed based upon his/her specific body functioning. This allows the maximum therapeutic dose of a particular drug to be administered within a small range of safety.

12: DRUG DEVELOPMENT IN THE UNITED STATES

12.1: New Chemical Entities

The FDA is approving new chemical entities (NCE's) for marketing in the U.S., at a rate of approximately one every two months. This represents an average of 21 new NCE's per year for the period 1975-1987 during which time 270 NCE's were approved by the FDA. A backlog of 73 applications was reported for 1986.

12.2: New Dosage Forms and Drug Delivery Systems

The systems and other mechanisms that "deliver" the chemical compound to the target site of drug action are broadly referred to as "drug delivery systems". Most common of these are tablets, capsules and liquids. Dosage forms are the variety of methods that are used to combine a chemical agent with an appropriate form so that it might be administered. Innovations in these areas have resulted in time-release syrups, skin-patches that deliver drugs transdermally, insulin pumps and ophthalmic inserts that release drugs over time. All of these efforts are targeted at more efficient delivery of the drug to desired areas of action.

12.3: "Biotech Drugs"

These products are drugs derived from "genetic engineering" and creative manipulation of proteins and other such compounds. Eighty one such products are currently under investigation. In contrast to the more traditional organic chemical synthesis, these products are derived in whole or in part from biological materials. As better understandings of the body's immune system become known, it is anticipated that more "biotechnology" products will become available for diagnostic and treatment purposes.

12.4: Orphan Drug Development

By Congressional action, certain incentives were put in place to

stimulate the development, manufacture and sale of drugs for rare diseases. The Department of Health and Human Services has defined a rare disease as less than 200,000 cases per year. At the end of 1987 (four years after the legislation was enacted), 183 drugs had been designated as orphans and 24 of these have been approved and are being marketed.

12.5: Economic Realities in the Drug Industry

Total prescription and non-prescription drug sales are placed at \$38 billion for 1987. An 8% growth is estimated for 1988 and estimates nearing 10% are projected for the next five years. The U.S. drug industry has been characterized as having the highest return on stockholders equity (1986) and among the highest total return on investment from among all industrial corporations in the U.S. The beverage and food industries are its closest rivals in profitability terms. It is thus a productive and powerful industry which on the one hand has contributed immensely to the health and welfare of the population and on the other hand works very hard at protecting its interest, sometimes by unscrupulous means (eg. Dalkon Shield). It is a small industry, however, with total sales less than some individual corporations (eg. IBM, GM).

The pharmaceutical industry markets primarily to prescribers. More recently however, the industry has moved to "direct to consumer" marketing techniques (inducing demand for

pharmaceuticals among professionals and the public is one of the industry's major marketing strategies). This is justified by the industry on the basis that profits derived from large sales allow continuous re-investment into research and drug discovery. For 1987, the PMA reported that 13% of sales and exports was reinvested in research. The reported cost of bringing a new drug to the marketplace is about \$100 million.

13: DRUG MISADVENTURING IN THE UNITED STATES

13.1: Morbidity, Mortality and other Epidemiological Markers

It has been reported that approximately 10% of hospital admissions are directly attributable to negative drug experiences or "drug misadventures". The medication error rate in hospitals is reported to be approximately 12%. Deaths are reported to occur in one out of a thousand patients admitted to hospitals directly related to drug iatrogenesis.

From among the Adverse Drug Reports submitted through the voluntary reporting system of the FDA, about 20% result in hospitalization and/or death.

While these figures may be dramatic, they are "soft" in that the U.S. does not have a uniform and more specific reporting systems for drug misadventuring. A glaring deficiency in the data available to date is information which describes drug misadventuring in the ambulant population. Moreover, accurate

data that describes total drug usage in the American population is not available.

It is known however, that negative drug experiences increase with age, with the advent of multiple chronic disorders and with multiple drug therapies used to treat such disorders. AARP data suggest that 40% of the elderly experience side effects with drugs although a qualitative factor describing such effects is not reported. 125,000 annual deaths have been reported in the U.S. directly consequent to legitimate drug use.

13.2: Public Policy Issues

As the number of available drug entities and their respective dosage forms continue to expand in both numbers and complexities, the American public is being faced with important choices. It is indeed not possible to remove the "risk from risk" and thus, an expanded drug armamentarium carries with it a certain degree of risk. In the case of pharmaceuticals, the attendant risk carries with it certain implications for other areas of the health care system. That is, drug misadventuring always leads to further medical care requirements and, usually hospitalization is mandated.

Emphasis has not been placed on the prevention of drug misadventuring in the U.S. outside of the normal callings for due diligence and care. Physicians are given wide latitude in their

prescribing practices in the U.S. and pharmacists have not gained sufficient cultural and legal authority to mediate the prescribing process. Moreover, significant induced demand for the use of drugs is created by the pharmaceutical industry and certain social "givens" (eg. there is a pill for every ill). Particularly for the elderly, "polypharmacy" (multiple drug therapies for multiple chronic conditions), introduces a potential harm element to the care of the patient. The sequelae to such practice are drastic with regard to demands that get placed on other areas of the health care system.

13.3: Minimizing Risk

All health care practitioners whose functions involve them in drug therapy must of course exercise due caution based upon contemporary knowledge of drugs and their respective contraindications and known side effects. Given the broad array of available drugs and their dosage forms in the U.S., it is unrealistic to think that all such practitioners have the necessary knowledge to prevent harm to the patient. A significant emphasis must be placed on the team approach to drug therapy, particularly in the elderly.

Patients also contribute to this problem by not fully knowing the extent to which their non-compliance with therapy plans contribute to drug misadventuring. Hence, patient education and follow through is highly desirable. End point counseling and

community-based management and monitoring of the patient is required to assure least harm.

13.4: Surveillance and Reporting

The United States maintains a system of voluntary reporting of Adverse Drug Effects through the U.S. Food and Drug Administration which is largely developed through reports of incidence submitted by physicians. Where physicians have submitted reports of adverse drug effects to the manufacturer of the implicated drug, the drug company is required by law to submit this information to the FDA. However, it is estimated that only ten percent of adverse drug incidents are reported.

Some experimentation is currently on-going to: i) increase the reporting of adverse drug incidents to the FDA by physicians, and ii) including a broader base of patient reporting as part of the formal reporting mechanism.

14: PHARMACY IN THE 21st CENTURY

In 1984, Project HOPE Institute for Health Policy in cooperation with the Institute for Alternative Futures, conducted a Strategic Planning Conference for the professional pharmacy community. The following reflects the basic findings of that conference.

14.2: Prognostications based on Continued Growth

Education--national consensus on the Doctor of Pharmacy degree as

the minimum entry-level educational credential, expansion of enrollments and faculty numbers, competency-based curricula with specialization tracking, expanded biological and physical science requirements due to complexity of drug development

Practice--cost-containment stays as a national priority, majority of pharmacists are employees, independent pharmacies replaced by chain companies, extensive use of technicians and automated systems in the filling of prescriptions, expanded release of legend drugs for non-prescription use, expensive drugs, greater involvement of pharmacists in therapeutic decision making.

14.3: Consensus Conference on Pharmacy as a Clinical Profession

Sponsored by the ASHP Research Foundation, a consensus conference convened in 1985 for the purpose of clarifying the underlying theory and practice of pharmacy as a clinical profession. Subsequent to this conference, regional conferences have been held throughout the country to further the general ideal of a more clinical role for the profession of pharmacy in all aspects of the drug use process.

SUGGESTED FURTHER READING

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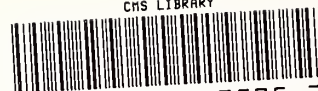
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